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10/521,513	11/18/2005	Roy R. Lobb	BII-00101	2848

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,513	LOBB, ROY R.	
	Examiner	Art Unit	
	JEGATHEESAN SEHARASEYON	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *10,105,108-111,113,114,119 and 133* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-72,74-77,79,80,85,99 and 139-148* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/26/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 70-72,74-77,79,80,85,99,105,106,108-111,113,114,119,133 and 139-148.

DETAILED ACTION

1. This Office Action in response to Applicant's amendments and remarks filed 9/26/08. Claims 70-72, 74-77, 79-80, 85, 99, 105-106, 108-111, 113-114, 119, 133 and 139-148 are pending. Claims 105-106, 108-111, 113-114, 119 and 133 are withdrawn. Claims 139-148 are newly added.

2. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

Information Disclosure Statement

3. The PTO-1449 provided on 9/26/08 has been partially considered. The English abstract provided in the references have been considered (The references are in Russian). The duplicate abstracts have not been considered.

Claim Rejections - 35 USC § 102, maintained

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4a. The rejection of claims 70, 71and 99 are under 35 U.S.C. 102(b) as being anticipated by Udea et al. (1990) is maintained for reasons set forth in the Office Action dated 4/16/08.

Applicant in the response filed 9/26/08 is asserting that Ueda et al. does not teach a method of treating glomerulonephritis in a mammal. Applicant assert that instead, Ueda et al. teaches that a treatment of hepatitis B with interferon-β. Contrary to Applicant's assertion, the reference teaches the treatment of glomerulonephritis caused by HBV in human patients (mammals) by administering interferon-β (abstract, p.1153). The reference also teaches that the HBV containing patients showed improvement in proteinuria (abstract). Further, contrary to Applicants assertion the Udea et al. reference identified the glomerulonephritis in patients using renal biopsies and direct immunofluorescence.for treatment. In addition, as discussed previously (Office Action of 4/16/08), the reference also teaches that these patients had membranous glomerulonephritis and proliferative glomerulonephritis. Further, the crescent formation in patients is disclosed in p. 1156. Thus, disclosing the treatment of crescentic glomerulonephritis using interferon-β. Improvements in proteinuria will inherently result in the treatment of glomerulonephritic conditions. The Office will address the obvious rejection below. In addition, claims 139-148 were newly added and will addressed below. Therefore, rejection of claims 70, 71 and 99 under 35 U.S.C. 102(b) as being anticipated by Udea et al. (1990) is maintained.

Claim Rejections - 35 USC § 103, maintained

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5a. The rejection of claims 70-72, 74-77, 79, 80, 85 and 99 under 35 U.S.C. 103(a) as being unpatentable over Udea et al. (1990) in view of Pedersen et al. (U. S Patent No. 6, 531, 122) is maintained for reasons set forth in the Office Action dated 4/16/08.

Applicant asserts that the combination of references do not teach or suggest all of the claimed limitations. Specifically, it is claimed that Ueda et al. does not teach or suggest a method of treating glomerulonephritis in a mammal; instead it is claimed that Ueda et al. teach the treatment of hepatitis B with interferon-β. It is also claimed that Pedersen et al. does not cure this deficiency. Applicant is also asserting that at the time of filing there existed no reasonable expectation of success that a method for treating glomerulonephritis in a mammal, comprising identifying a mammal having glomerulonephritis and administering to the mammal a therapeutically effective amount of an interferon-β therapeutic, would be effective, absent the teachings of the present specification. Contrary to Applicant's assertions as discussed above in paragraph 4a. Ueda et al. reference teaches the treatment of glomerulonephritis caused by HBV in

human patients (mammals) by administering interferon-β (abstract, p.1153). The reference also teaches that the HBV containing patients showed improvement in proteinuria (abstract). Further, contrary to Applicants assertion the Udea et al. reference identified the glomerulonephritis in patients using renal biopsies and direct immunofluorescence.for treatment. In addition, as discussed previously (Office Action of 4/16/08), the reference also teaches that these patients had membranous glomerulonephritis and proliferative glomerulonephritis. Further, the crescent formation in patients is disclosed in p. 1156. Thus, disclosing the treatment of crescentic glomerulonephritis using interferon-β. Improvements in proteinuria will result in the treatment of glomerulonephritic conditions. Pedersen et al. reference taught various forms of interferon-β used in the instant invention. Therefore, one of ordinary skill in the art would have been motivated to use the methods of Udea et al. to treat glomerulonephritis by administering modified interferon-β because Pedersen et al. disclose that mature modified interferon-β functions similar to unmodified mature interferon-β

Further, there is reasonable expectation of success because Udea et al. reference clearly teaches that interferon-β improves the clinical outcome of glomerulonephritis patients specifically with the reduction of proteinuria. The rationale for using modified interferon-β of Pedersen et al. is to reduce the allergenicity (column 2) and increase the circulating half life of the protein. One of ordinary skill in the art would have been motivated use the dosages used in Udea et al. because they are clinically effective. With respect to Applicant's arguments pertaining to claims140-144

and 148, these are newly added claims with new claim limitations which were not addressed previously. For example, glomerulonephritis not caused by hepatitis virus. These are addressed in the rejection below. Clearly, Udea et al. teaches glomerulonephritis associated with a virus. Therefore, the rejection of instant invention as being *prima facie* obvious over Udea et al. (1990) in view of Pedersen et al. (U. S Patent No. 6, 531, 122) is maintained.

6. New rejections necessitated by Applicant's addition of new claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7a. Claims 70-72, 74-77, 79, 80, 85 and 139-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarting et al. (2001, PTO 1449 of 6/2/06) in view of Pedersen et al. (U. S Patent No. 6, 531, 122) and Chang et al. (U. S Patent No. 5, 908, 626).

Instant invention is drawn to a method of treating glomerulonephritis in mammals by administering interferon-β.

Schwarting et al. (2001) teaches the use of interferon-β in the treatment of lupus nephritis in a mammal. Specifically, it teaches the prophylaxis and therapy of lupus caused (non-viral) glomerulonephritis in MRL-*Fas*^{lpr} mice. Reference teaches that with interferon-β treatment there is improved renal function (serum urea) and histopathology (infiltrating leucocytes, IgG-deposition) as compared to PBS controls. However, the reference does not teach interferon-β of SEQ ID NO: 4.The reference also does not teach a glycosylated interferon-β or pegylated interferon-β. In addition, the Schwarting et al. reference does not disclose interferon-β-1b or a heterologous polypeptide with immunoglobulin (Ig) molecule.

Pedersen et al. teach various interferon-β preparations. The Pedersen reference teaches mature interferon-β of SEQ ID NO: 2 (columns 1- 3) which is identical to SEQ ID NO: 4 of the instant invention. This meets the limitations of claims 75 and 76. The glycosylation of interferon-β is disclosed (column 2). This meets the limitation of claim 77. Interferon-β-1a and interferon-β-1b are also disclosed (column 2) meeting the limitation of claims 79 and 80. The pegylation of interferon-β is also discussed (column 4 and entire patent).

Chang et al. disclose interferon-β-Fc fusion protein (columns 1 and 2). This meets the limitations of claims 145 and 146.

Therefore, it would have been *prima facie* obvious at the time of the invention to modify the treatment methods of Schwarting et al. to treat glomerulonephritis in mammals by administering various interferon-β molecules as disclosed in Pedersen et al and Chang et al. One of ordinary skill in the art would have been motivated to use the methods of Schwarting et al. to treat glomerulonephritis by administering modified interferon-β because Pedersen et al. and Chang et al. disclose that mature modified interferon-β functions similar to unmodified mature interferon-β.

Further, there is reasonable expectation of success because Schwarting et al.. reference clearly teaches that interferon-β improves the clinical outcome of lupus induced glomerulonephritis in mammals specifically with the improved renal function (serum urea) and histopathology (infiltrating leucocytes, IgG-deposition). The rationale for using modified interferon-β of Pedersen et al. and Chang et al. is to reduce the allergenicity (column 2, Pedersen) and increase the circulating half life of the protein (Chang et al., column 2) . One of ordinary skill in the art would have been motivated use the dosages used in Schwarting et al.. because they are clinically effective. Therefore, the instant invention is *prima facie* obvious over Schwarting et al.. (2001) in view of Pedersen et al. (U. S Patent No. 6, 531, 122) and and Chang et al. (U. S Patent No. 5, 908, 626).

Conclusioni

8. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEGATHEESAN SEHARASEYON whose telephone number is (571)272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/
Primary Examiner, Art Unit 1647

JS